

## **MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAM**

### **APPLICATION AND CONTRACTING PROCESS SUMMARY**

#### **Background**

The Centers for Medicare and Medicaid Services is developing the processes it will use to contract with entities that will offer outpatient prescription drug benefits (also referred to as “Part D benefits”) to eligible Medicare beneficiaries. Medicare beneficiaries electing Part D coverage will receive their prescription drug benefits through Prescription Drug Plans (PDPs), Medicare Advantage Prescription Drug Plans (MA-PDs), or Fallback Plans.<sup>1</sup> This paper provides a discussion of CMS’ plans for soliciting and reviewing applications and bids from entities interested in participating in the Part D program.

The Medicare Modernization Act requires that coverage under prescription drug plans and MA-PD plans will be effective on January 1, 2006. As part of the program’s implementation process, CMS published a draft Part D regulation on August 3, 2004 and accepted public comments on the draft through October 4, 2005. We are currently reviewing the comments and drafting the final regulations, to be published in early 2005. Concurrently, CMS is developing the procedures for implementation of the Part D program. Because many operational policies are still under consideration during the rulemaking process, this document and the accompanying draft solicitation cannot provide a complete discussion of all the application and bid requirements Part D sponsors will have to meet. However, because the implementation timeline will be very tight for both CMS and its Part D contractors, we believe it is useful to let potential Part D applicants know the application and bid plans we have developed so far. This information will allow potential Part D sponsors to begin to make their plans for responding to our solicitations beginning in the spring of 2005. Also, the comments we receive will inform our drafting of the final solicitation and bid requirements, making it more likely that CMS will develop requirements that make sense to current participants in the prescription drug benefit industry.

CMS invites comments from potential Part D applicants on the application and bid process described in this document. Please send your comments to [drugbenefitimpl@cms.hhs.gov](mailto:drugbenefitimpl@cms.hhs.gov) by December 30, 2005.<sup>1</sup> Comments relating to the rationale for or the legal basis of the substantive policies underlying this document were due on October 4, 2004 in response to the Part D proposed rule published August 4, 2004. Comments that question or request modification to the substantive, underlying policies of the NPRM will not be considered. In commenting, please provide a contact name and phone number for any follow up by CMS.

**NOTE about Employer Only Plans** : Waivers are available to facilitate the offering of MA, MA-PD and PDP plans by employers, labor organizations, or the trustees of a fund

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<sup>1</sup> Any special requirements or waivers for PACE, Private fee-for-service (PFFS) and 1876 cost reimbursement plans offering Part D drug coverage will be integrated into the MA-PD application.

established by one or more employers or labor organizations to furnish benefits to the entity's retirees. These employer plans can be offered either through an employer contract with an MA-PD or a PDP, or through direct employer sponsorship of a PDP or MA-PD for its retirees only. We are currently assessing the most efficient way to implement these waivers to facilitate employer flexibility in retaining retiree coverage. We anticipate that the employer only waiver guidance will be available in the near future. In this guidance we will advise employers, PDPs and MAs of the process we will use to approve employer group waiver requests and the general employer group applications process.

### **Types of Part D Contractors**

As noted above, the Part D program authorizes CMS to contract with three different types of entities to administer the prescription drug benefit, PDPs, MA-PDs, and Fallback Plans. CMS will develop separate solicitations for each type of sponsor. This paper will discuss primarily the PDP application process as the MA-PD and Fallback Plan solicitations largely will be variations of the PDP requirements. Following is a description of the three types of Part D sponsors:

*Prescription Drug Plan (PDP) Sponsor:* A Medicare contractor that accepts payment from CMS on a risk or limited risk basis to provide Part D drug coverage to Medicare beneficiaries who obtain their medical coverage through Medicare fee-for-service, an MA-MSA plan, an MA private fee-for-service (PFFS) plan, or a cost plan that does not offer Part D drug coverage.

*Medicare Advantage – Prescription Drug (MA-PD) Sponsor:* A Medicare contractor that provides Part D coverage with its coverage for Part A and Part B services through a Medicare Advantage plan.

*Fallback Plan:* A Medicare contractor that accepts reimbursement from CMS on a cost and performance guarantee basis for providing Part D coverage to Medicare beneficiaries who reside in an area where the statutory plan access standards are not met (i.e., an area that is not served by a) at least two PDP sponsors or b) one PDP sponsor and an MA-PD sponsor.)

### **Application and Bid Process**

#### *PDPs*

CMS' selection of PDPs to participate in the Part D program will be conducted in two stages, the application process and the bid process. In late January 2005, CMS expects to release a final solicitation for applications for entities seeking a contract to operate as a PDP sponsor. Soon after posting the applications, CMS will hold a pre-application conference at CMS' Central Office in Baltimore. (We are also considering two additional conferences, each in a different location.) At the conference, potential

applicants will have the opportunity to ask questions. CMS staff will also respond to questions submitted by e-mail. Answers to questions from the conference as well as questions submitted after the conference will be posted on the CMS web site throughout the application period. Also, CMS expects to conduct weekly telephone conference calls to respond to questions from potential applicants.

Applications will be due to CMS by approximately mid-March. We intend to provide applicants at least 45 days, and as close to 60 days as possible, to respond to CMS' solicitation. CMS will review applications during the spring of 2005. Successful applicants will be notified in late spring whether CMS has deemed their organization eligible to enter into a Part D contract. Unsuccessful applicants will be issued a notice of intent to deny and given an opportunity to cure the deficiencies in their applications. Applicants who are still unsuccessful at that point will be issued an application denial by CMS and informed about their rights to reconsideration under the MMA.

To facilitate the timely review of all the bid submissions, CMS expects to require Applicants to submit the portion of their bid related to formulary and covered drugs on April 18, 2005. CMS will review areas of each proposed drug plan formulary by tier and drug availability and evaluate each element against evidence-based metrics such as widely accepted Treatment Guidelines. CMS intends to complete as many of the formulary reviews as possible (at least two weeks) before the June 6, 2005 bid submissions so that any necessary formulary modification may be reflected in those documents.

All PDP applicants will be required to submit bids for their plans on June 6, 2005. The PDP bids will contain the pricing, benefit, and service area information for each of the plans the PDP sponsor wishes to offer during the 2006 program year. PDP sponsors will submit their bids electronically through CMS' Health Plan Management System (HPMS).

CMS will review each of the bids to make certain that they are actuarially equivalent to the standard Part D benefit and to ensure that they are not designed to exclude certain types of beneficiaries. CMS will then calculate a benchmark premium for each Part D region based on an average of all the premiums submitted in that region. More detailed information about the bid process will be posted at a later date and separately from the solicitation.

Once CMS has approved all of the bids at the end of the summer of 2005, PDP sponsors will be required to execute a Part D contract and submit their marketing materials to CMS (or its contractor) for review and approval. Also, CMS will include information about each approved plan in CMS' own outreach materials for Medicare beneficiaries. (Fallback plans are precluded from conducting their own marketing activities.)

PDP sponsors will be required to begin accepting enrollments on November 15, 2005 and to begin offering Part D benefits to their plan enrollees on January 1, 2006.

### MA-PDs

Under the MMA, Medicare Advantage coordinated care plans contractors (and PFFS plans at their option) must offer at least one plan throughout their service areas that includes prescription drug coverage under Part D. MA contractors will be required to apply for qualification to offer a Part D plan as part of their MA application if they are a new participant in the MA program. If the MA organization is transitioning from a previous Medicare managed care contract, the Part D application will simply be a stand-alone submittal. CMS will post the Part D portion of the MA application on the same date that it posts the PDP application. MA sponsors can expect the Part D portion of the MA application to be an abbreviated version of the PDP solicitation, as the regulation allows CMS to waive provisions that are duplicative of MA requirements or where a waiver would facilitate the coordination of Part C and Part D benefits.

Prospective MA-PD sponsors will be required to submit separate bid components for their Part C and Part D plan offerings. We anticipate that the MA and Part D application and bid reviews will be conducted according to approximately the same timeline.

### Fallback Plans

The MMA requires CMS to contract with Fallback entities according to the provisions of the Federal Acquisition Regulation (FAR). Therefore, we intend to conduct a competitive application process in two parts.

First, CMS will publish a Statement of Work that will contain many of the same requirements as described in the PDP solicitation. The applicants will be required to demonstrate that they meet the requirements to be a fallback entity, including that they have the capability to offer a Part D plan in any region for which they are applying. From the applicants, CMS will select a limited number of entities with which to contract to provide fallback plan services.

The MMA also states that entities seeking a Fallback Plan contract may not have been an applicant or a subcontractor to an applicant for qualification as a PDP plan. CMS will be looking closely at the entities that apply for a Fallback Entity contract as well as their applications to identify situations where applicants have set up “sham” arrangements to evade this prohibition.

Second, after it has completed the bid review process for PDPs and MA-PDs, CMS will issue task orders for those regions or partial regions where there are not at least two PDPs or one PDP and an MA-PD available to beneficiaries. The successful respondent to each task order will be offered a contract to serve the identified Part D Region.

### Timeline

The following is a draft timeline for implementation of the Medicare Part D program. The first timeline displays the deadlines associated with the PDPs and MA-PDs. The second displays the deadlines associated with the Fallback Plan implementation.

***Special Note Regarding Licensure Requirement*** – PDP and MA-PD applicants should be aware that the MMA and the proposed regulations issued pursuant to MMA provide that CMS may enter into Part D contracts only with those entities that are licensed as risk-bearing entities in the States in which they propose to offer their Medicare benefit plans. The MMA and the regulations authorize CMS to grant waivers of this requirement when certain requirements are met. Among the bases for waiver is the failure by a State to act on an application for licensure within 90 days of a completed application being submitted to the appropriate State agency. CMS can act on such a waiver request only upon the expiration of this 90-day period. **To meet the anticipated PDP and MA-PD deadlines, parties interested in submitting a PDP or MA-PD application must begin consulting immediately with the appropriate State authorities about the process for obtaining the required State license.** CMS does not have the authority to enter into a contract with an applicant that does not meet the requirements for a licensing waiver.

#### PDP and MA-PD Implementation

<b>Date</b>	<b>Milestone</b>
Late January 2005	Posting of PDP, MA-PD, and Fallback Plan solicitations on CMS web site.
Late January 2005	Begin registration for Pre-Application Conferences.
Early February 2005	Pre-Application Conferences
Early February 2005	Submit notice of intent to apply to CMS.
March 2005	Applications due to CMS approximately 60 days after solicitations are posted.
May/June 2005	CMS sends Part D contract eligibility determination to Applicants.

#### Formulary Bid and Contracting Process

<b>Date</b>	<b>Milestone</b>
March 2005	CMS conducts detailed bid training for Applicants.
April 1, 2005	Applicants receive instructions to download Plan Benefit Package and Pricing Tool from the Health Plan Management System (HPMS). Applicants may begin submitting their bids.
April 18, 2005	Applicants submit formularies to CMS for review.
May 16, 2005	CMS provides preliminary approval of formularies.
June 6, 2005	PDP and MA-PDP sponsors submit bids to CMS for each of the Part D plans they propose to offer during 2006. Disapproved applicants requesting a reconsideration of CMS' determination must submit their bids on this date as well.
June 6, 2005 through July 24, 2005	Modifications to bids accepted only at the discretion of CMS.

July 2005	Training on submission of drug claims data to CMS.
July 24, 2005	CMS provides preliminary approval/disapproval of bids.
August 2, 2005	CMS publishes national average Part D premium, and MA regional bid benchmarks are calculated.
September 2, 2005	CMS completes review and approval of bid data. CMS executes Part D contracts with qualified Applicants who submit an acceptable bid.

### Pre-Implementation and Implementation Process

<b>Date</b>	<b>Milestone</b>
Early Spring 2005	Begin weekly Applicant/PDP sponsor/MA-PD sponsor technical support calls with CMS.
Early Spring 2005	Begin testing between PDP sponsors and CMS on information systems interfaces and data exchanges.
September 2005	Training on enrollment and payment.
November 15, 2005	Part D initial enrollment period begins for individuals who are first eligible to enroll in a Part D plan on or prior to January 31, 2006.
January 1, 2006	Medicare beneficiaries begin receiving drug benefits from Medicare Part D contractors.
May 15, 2006	Initial enrollment period ends for individuals who are first eligible to enroll in a Part D plan on or prior to January 31, 2006.

### Fallback Plan Implementation

<b>Date</b>	<b>Milestone</b>
Late January, 2005	Fallback Plan statement of work synopsis published in Federal Register
Late January, 2005	Registration for Pre-Application Conference.
Early February, 2005	Pre-Application Conference.
Mid March, 2005	Technical proposals due to CMS.
April 2005	Applicants within the competitive range make oral presentations to CMS review panel.
May 30, 2005	CMS completes evaluation of technical proposals; negotiates to enter into contracts with successful applicants.
June 2005	Task orders issued for regions to be served by Fallback Plans.
July 2005	Task order proposal due back to CMS.
September 2005	Successful Fallback Plan applicants announced. CMS enters into contracts with successful applicants.

### Overview of Solicitations

As noted above, the solicitation released with this overview of the application process reflects the fact that some significant portions of the Part D regulation are still in development. Below is a discussion of some of the topics Part D applicants can expect to have to address, topics that require significant additional CMS development, and a request for comments on how application standards can be developed that would best serve the Part D contractors and their Medicare enrollees.

For many operational areas, the Applicant will be required simply to attest that it will comply with a particular set of qualifications in operating its Part D benefit plan(s). Applicants who enter into Part D contracts with CMS will be required to maintain documentation of their compliance with these qualifications (e.g., written policies and procedures) and produce such documentation upon CMS' request.

### PDP Solicitation

#### Licensure, Financial Stability

- CMS is developing the process applicants will use to request a waiver of the State licensure requirements. Parties interested in submitting a PDP or MA-PD application should note that CMS does not have the authority to enter into a contract with an applicant that does not meet the requirements for a licensure waiver. Such parties must begin consulting immediately with the appropriate State authorities about the process for obtaining the required State license. (*See Special Note under "Timeline" above.*)
- See related papers entitled, "*Request for Federal Waiver of State Licensure Requirement for Prescription Drug Plan (PDP)*", and, "*Requirements for and Contracts with Prescription Drug Plan (PDP) Sponsors: Federal Solvency Standards for PDP Sponsors who Meet Standards for Waiver for State Licensure*". These papers present our draft waiver requirements and financial stability requirements that applicants will have to meet if they are granted a waiver of the State licensure requirement.

#### Benefit Design

- See related paper entitled, "*CMS Strategy for Reviewing Formulary including the Operation of Plan Policies and Procedures Affecting Access to Drugs Covered under MMA*", which discusses our draft formulary review strategy.
- Related to that strategy, the final solicitation will ask applicants for some basic information about the tools they will use to build and operate their benefit packages. Applicants will be asked to discuss utilization management, and their pharmacy and therapeutics committee. More detailed information specific to each benefit package will be requested as part of each successful applicant's bid.

#### Service Area/Regions/Pharmacy Network

- CMS continues to consider options for the establishment of the PDP and MA-PD regions. This includes consideration of the Part D plan service in the U.S. Territories.
- CMS continues to options for ensuring access to Part D benefits for residents of long-term care facilities.
- We expect to publish the regions by *[INSERT DATE]*.

#### Enrollment and Eligibility

- PDP contractors will be required to accept applications from beneficiaries and interact with CMS systems to verify Part D eligibility and make enrollments effective.

#### Grievances and Appeals

- Applicants will be required to describe their policies and procedures for educating beneficiaries about their grievance, exception and appeal rights and for ensuring that beneficiary appeals are adjudicated in a manner consistent with the requirements of the Part D final rule.

#### Coordination of Benefits

- CMS is developing policies and procedures Part D sponsors will be required to coordinate prescription drug payments from other insurers.

#### Tracking True Out-of-Pocket Costs

- CMS is considering options for the most efficient system for tracking beneficiary drug spending. This may involve CMS creating a central database to with which Part D sponsors would interact to make certain that beneficiaries are charged appropriate deductibles and coinsurance.

#### Medication Therapy Management

- CMS is currently considering comments submitted in response to the draft Part D regulation as it develops the standards for medication therapy management.

#### Electronic Prescribing

- CMS is developing e-prescribing standards that will be published in regulation form in the Federal Register. These standards will be incorporated into the solicitation when they become effective.



### Marketing/Beneficiary Communications

- Applicants will be required to acknowledge that they will adhere to CMS' Part D marketing guidelines in conducting their marketing activities. The guidelines are expected to be completed in the spring of 2005.
- Applicants will be required to attest that they will operate enrollee and provider call centers consistent with CMS standards.

### Control Fraud, Waste, and Abuse

- Applicants will be required to indicate that they will implement policies and procedures designed to detect and prevent fraud, waste, and abuse related to the Part D program.

### Reporting Requirements

- CMS is still developing the standards concerning the type, frequency, and format for reporting of Part D operation data for compliance and payment purposes. Reporting requirements will likely include claims data and will reflect data needed for both CMS monitoring and payment purposes.

### Information Systems

- Applicants will be required to establish connectivity with CMS for four purposes: maintenance of the Health Plan Management System, enrollment, claims data submission and payment.
- Applicants will establish HPMS connectivity prior to submitting their applications.
- Enrollment and payment system connectivity will be established according to instructions CMS will release in the spring and summer of 2005.

### Privacy

- Applicants will be required to comply with the HIPAA Privacy Rule as it applies to health plans and as it applies to business associates for the purpose of administering the low-income subsidy.

### Security and Record Retention

- Applicant has, as of the initial enrollment date, appropriate administrative, technical, and physical safeguards in place to protect the privacy of protected health information in accordance with 45 CFR §164.530(c), and meets the

standards, requirements, and implementation specifications as set forth in 45 CFR part 164, subpart C, the HIPAA Security Rule prior to beginning enrollment of beneficiaries.

- Applicants will be required to attest that they will maintain records associated with the operation of their Part D plans for at least six years following the termination of their Part D contract. Applicants will also be required to describe their record retention policies and procedures.

#### MA-PD Solicitation

As noted above, prospective MA-PD sponsors will submit their Part D application as part of their MA application unless they are a transition plan. A transition plan is a plan offered under an existing contract. For transition plans, the Part D application will be separate. The Part D solicitation will identify those PDP sponsor requirements that CMS has decided to waive for MA-PD Applicants because the requirements either conflict with or duplicate MA program requirements or the waiver would promote the coordination of Part C and Part D benefits by the MA-PD sponsor. Waivers will not be granted where they would have the effect of compromising the value of the drug benefit contemplated under MMA. The MA-PD solicitation will also afford Applicants the opportunity to request waivers using the same coordination of benefits or conflicting/duplicative requirements justifications. Once approved by CMS, these waivers will be applicable to every similarly situated MA-PD sponsor. All of the approved waivers (both CMS and Applicant-initiated) will be reflected in the MA-PD sponsors contracts each approved entity will be required to sign.

CMS anticipates granting waivers on its own initiative of the specific requirement listed under the following areas. Please note that this list is not exhaustive, and CMS reserves the right to revise the list at any time prior to the posting of the final MA-PD solicitation.

#### Licensure, Financial Stability

- MA organizations are already required to be licensed as risk-bearing entities.

#### Service Area

- MA-PDs will be required to meet MA provider access requirements for their pharmacy networks, not the TRICARE standard.

#### Information Systems

- MA-PDs will be required to establish HPMS connectivity for their Part C operations.

#### Privacy

- MA-PDs will have to comply with the HIPAA Privacy Rule for their Part C operations.

#### Security and Record Retention

- MA-PDs will have to comply with Federal information security requirements for the Part C operations.
- MA-PDs will have to retain for six years their records associated with the operation of their Part C plans.

#### Fallback Plan Solicitation

The Fallback Plan application qualifications will be similar to those of the PDP application. However, the application requirements of the solicitation will require more substantive responses than the simple attestations or affirmations required in a PDP application. Because the Fallback Entity contracting process is conducted on a competitive basis, CMS will ask for a more detailed description of each Applicant's capacity to perform a particular operational requirement so that it can compare responses and select the strongest candidate.

CMS is considering developing competitive review criteria that can be used to evaluate fallback plan applicants' capabilities in the areas of customer service, IT/data management, prescription drug management, pharmacy network, mail order, and financial solvency. Because fallback entities/applicants will likely have to begin their Part D operations on comparatively short notice, CMS will develop a comparison for implementation plans and start-up capabilities. Fallback entities/applicants will also be expected to compete on cost and, like the PDP and MA-PD sponsors, will have to present formularies that are not discriminatory and bids that pass an actuarial equivalence test. CMS expects to evaluate fallback plan applicants on the extent to which they can provide guarantees of performance tied to particular incentives. In developing all of these possible review criteria, CMS is carefully considering the public comments on these topics provided in response to the proposed Part D regulation.

The Fallback Entity solicitation will not require the Applicant to address the following PDP requirements.

#### Licensure, Financial Stability

- Fallback entities/applicants are not required to be licensed as a risk-bearing entity in the state(s) in which they operate. However, Fallback Plan Applicants will be required to meet CMS' financial solvency and capital adequacy standards.

#### Marketing/Beneficiary Communications

- Fallback entities are not permitted to market their Part D plans to Medicare beneficiaries.